95P-0077
CPI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1997

Mr. Alan Magazine, President
Health Industry Manufacturers Association
1200 G Street, NW, Suite 400
Washington, D.C. 20005-3814

Dear Mr. Magazine:

This is in response to HIMA's March 17, 1995 Citizen's Petition submitted to the Food and Drug Administration (FDA). FDA and HIMA representatives have discussed many of the recommendations of the petition in our on-going dialogue, but we thought a formal reply would be useful as well.

FDA appreciates and shares HIMA's concern for the protection and enhancement of the public health through appropriate regulation of medical technology. We at the Center for Devices and Radiological Health (CDRH) are also concerned about the many points presented in your petition.

We have reviewed and summarized the points of your petition. Briefly, as we interpret your petition, HIMA wants FDA to use a more common sense approach when reviewing medical device submissions, to improve timeliness, and to show a greater sensitivity in compliance issues. Listed in the attachment are many initiatives that we have undertaken since your petition was submitted to address concerns raised in your petition. We believe that these initiatives have addressed many of your concerns. In light of these many accomplishments, and given your recent submission to FDA (joined by other trade associations) listing industry's current priorities for administrative or legislative reform, we believe it appropriate to close out the docket on your Citizen's Petition.

We appreciate the time and effort that went into the preparation of this petition. We are very interested in continuing to work with you to improve the regulatory process. If you have any questions regarding this response, please call me at 301-443-4690.

Sincerely yours,

D. B. Burlington

D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health

cc: James Benson

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ATTACHMENT

RESPONSE TO
HIMA CITIZEN PETITION (95P-0077)

In response to the "Action Requested" section of the March 17, 1995 HIMA Citizen Petition, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) cites the following agency initiatives:

Medical Device Submissions and Review

FDA has reduced review times for device submissions:

510 (k)s:

In FY 1996, average FDA 510 (k) review time was 110 days, down from peak average review time of 184 days in 1994;

Backlog of 510(k)s under review for more than 90 days now totally eliminated and virtually non-existent for over one year; and

Pilot program for third party reviewers: Private reviewers available to conduct primary scientific review of 510(k)s for certain low and moderate risk devices (pilot study involves 7 outside organizations representing private, state government and international sectors).

IDEs:

FDA encourages sponsors to consult with FDA before they begin their studies; reviewers are keeping in touch during review process; this has resulted in improved submissions;

In FY 96, 70% IDEs approved within first 30 days of submission--more than double the figure for FY 94;

FDA has issued a proposed regulation to expand the use of promising devices for desperately ill patients: (Treatment IDE proposal) (December 19, 1996); and

FDA has issued a final regulation for informed consent, permitting waiver of informed consent requirements in certain emergency research (October 2, 1996).

PMA Supplements

Pilot program for "real time review" (e.g., 2 weeks or less) of supplements has resulted in dramatic review time reduction (5 days in some cases);

Reduced number of overdue PMA supplements to 17 in FY 96, down from 49 in FY 95 from a peak of 173 in FY 93; and

Pilot study for manufacturers of PMA-approved devices who request approval for site change.

PMAs

Approved 43 PMAs in FY 96, 24 were for new technologies-- this is twice annual approval rate for new technologies over past 15 years;

FDA is having more and earlier communications with manufacturers at the clinical study stage;

FDA has instituted project-managed tasks for review: establishing target dates (including advisory panel meetings) in advance; forming expanded review team early in process; reviewing labeling earlier in review process; and

To assure that submissions requirements are commensurate with the level of risk of the device, FDA has updated its reclassification procedures and held (jointly with HIMA) a public workshop.

Other

To facilitate more expeditious review of submissions, FDA works closely with national and international standards-setting groups (ANSI, ISO, and related organizations); and

FDA has issued a final regulation for humanitarian devices to permit an expedited route to market for devices serving very small populations (June 26, 1996).

Compliance Issues

FDA has issued a final regulation governing Good Manufacturing Practices (GMP) (October 7, 1996). Under this new GMP Quality Systems Regulation, design controls will be consistent with ISO 9001 and will be enforced after 6/98, paralleling the European mandatory controls date;

FDA published an October 8, 1996 Federal Register notice which amends draft guidelines on off-label use and allows device sponsors to disseminate information on off-label uses through peer reviewed journals and textbooks as long as articles clearly state that some data are for off-label use;

FDA is implementing the new export law which provides manufacturers greater latitude to export devices not approved in the U.S.;

FDA reassesses its enforcement priorities for the agency's medical device program annually and is now basing the enforcement initiatives on the potential risk to the public health and safety. Risk factors focus on issues such as whether or not a device group is life supporting or life sustaining, device classification, recall data, MDR data, and inspectional histories;

FDA prioritizes recurring inspectional obligations by product class and inspectional history; firms that intentionally or repeatedly fail to comply with relevant regulatory requirements are managed through Compliance Program 7382.830 - "Inspection of Medical Device Manufacturers." FDA's Warning Letters which are issued to recidivist firms identify the administrative and possible legal consequences of non- compliance and routinely request that the company use an outside consultant to resolve their regulatory deficiencies;

FDA is providing manufacturers with numerous new GMP educational offerings: manuals, guidance, videotapes, teleconferences, workshops;

FDA is developing a design control inspection strategy and will provide manufacturers with a list of questions that will be asked during inspections;

Office of Regulatory Affairs (ORA) and CDRH have implemented a pilot program so that FDA's record of inspectional observations could be discussed and annotated to note corrections that were completed or promised. This pilot also included advance notice/scheduling of routine inspections, as well as, close out" letter following inspections. This

program was announced in the April 3, 1996 Federal Register;

In a letter dated March 18, 1996 from the agency's Deputy Commissioner for Policy to HIMA's counsel, FDA eliminated the reference list as part of the Reinventing Government Program. New procedures (effective May 1, 1995) were published on May 4, 1995, as part of Compliance Program 7382.830 (see March 18, 1996 letter);

CDRH notified HIMA that, until regulations were published following notice and comment, the Center would not rescind 510 (k) clearances except under narrowly defined circumstances; and

The agency 1) encourages the use of third parties to certify compliance with GMPs for firms that have repetitive violative inspections; 2) has incorporated this process into the terms of voluntary consent decrees involving firms with chronic serious GMP violations; and 3) is evaluating the potential role of third party certification in other situations.